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Dkt. 50995-B/JPW/EMW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Riccardo Dalla-Favera
Serial No. : 09/585,023
Filed : June 1, 2000
For : IDENTIFICATION OF GENES ALTERED IN MULTIPLE MYELOMA

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1185 Avenue of the Americas
New York, New York 10036
September 5, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

INFORMATION DISCLOSURE STATEMENT

Applicant submits herewith an Information Disclosure Statement under 37 C.F.R. §1.56 and §1.97(b)(3).

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following disclosures, which are listed on Form PTO-1449 (**Exhibit A**):

1. Bakhshi, A., Jensen, J.P., Goldman, P., Wright, J.J., McBride, O.W., Epstein, A.L., and Korsmeyer, S.J. (1985) "Cloning the Chromosomal Breakpoint of t(14;18) Human Lymphomas: Clustering Around J_H on Chromosome 14 and Near a Transcriptional Unit on 18 Cell 41(3):889-906.
2. Bhatia et al., (1995) "Mutations in the Coding Region of c-myc

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Occur Independently of Mutations in the Regulatory Regions and are Predominantly Associated with myc/Ig Translocation", Current Topics in Microbiology and Immunology, 194:389-398.
(Exhibit 1)

3. Cleary, M.L. and Sklar, J. (1985) "Nucleotide Sequence of a t(14;18) Chromosomal Breakpoint in Follicular Lymphoma and Demonstration of a Breakpoint-Cluster Region Near a Transcriptionally Active Locus on Chromosome 18", Proc. Natl. Acad. Sci. USA 82(21):7439-7443.
4. Dalla-Favera, R., et al., (1982) "Human C-Myc Onc Gene is Located on the Region of Chromosome 8 That is Translocated in Burkitt Lymphoma Cells", Proc. Nat. Acad. Sci. USA 79(24):7824-7827.
5. Databases EMBL/GenBank/DDBJ on MPSRCH, Grossman et al., Accession number U5268219, 19 April 1996.
6. Dewald, G.W., et al., (1985) "The Clinical Significance Of Cytogenetic Studies In 100 Patients With Multiple Myeloma, Plasma Cell Leukemia, Or Amyloidosis", Blood 66(2):380-390.
7. Driggers, P.H., et al., (1990) "An Interferon γ -Regulated Protein That Binds the Interferon-Inducible Enhancer Element of Major Histocompatibility Complex Class I Genes", Proc. Natl. Acad. Sci. USA 87(10):3743-3747.

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8. Eisenbeis, C.F., et al., (1995) "Pip, A Novel IRF Family Member, is a Lymphoid-Specific, PU.1-Dependent Transcriptional Activator", Genes & Dev. **9(11)**:1377-1387.
9. Eton, O., Scheinberg, D.A., and Houghton, A.N. (1989) "Establishment and Characterization of Two Human Myeloma Cell Lines Secreting Kappa Light Chains", Leukemia **3(10)**:729-735.
10. Fiedler, W., Weh H.J., and Hossfeld, D.K. (1992) "Comparison of Chromosome Analysis And BCL-1 Rearrangement in a Series of Patients With Multiple Myeloma", Br. J. Haematol. **81(1)**:58-61.
11. Gould, J., et al., (1988) "Plasma Cell Karyotype in Multiple Myeloma", Blood **71(2)**:453-456.
12. Grant, C.E., Vasa, M.Z., and Deeley, R.G. (1995) "cIRF-3, a New Member of the Interferon Regulatory Factor (IRF) Family That is Rapidly and Transiently Induced by dsRNA", Nucleic Acids Res. **23(12)**:2137-2146.
13. Iida, S., et al., (1993) "MLLT3 Gene on 9p22 Involved in t(9;11) Leukemia Encodes a Serine/Proline Rich Protein Homologous to MLLT1 on 19p13", Oncogene **8(11)**:3085-3092.
14. Jernberg, H., Zech, L., and Nilsson, K. (1987) Cytogenetic Studies on Human Myeloma Cell Lines Int. J. Cancer **40(6)**:811-817.

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15. Kobyashi et al., (1995) "Overexpression of the PRAD-2 Oncogene in a Patient with Multiple Myeloma and T(11-14) (q13; q32;q31)", ACTA Haematologica, **94(4)**:199-203. (Exhibit 2)
16. Kozak, M. (1989) "The Scanning Model for Translation: an Update", J. Cell. Biol. **108(2)**:229-241.
17. Matsuyama, T., et al., (1995) "Molecular Cloning of *LSIRF*, a Lymphoid-Specific Member of the Interferon Regulatory Factor Family That Binds the Interferon-Stimulated Response Element (ISRE) Nucleic Acids Res. **23(12)**:2127-2136.
18. Mazars, G-R., et al., (1992) "Mutations Of The p53 Gene In Human Myeloma Cell Lines", Oncogene, **7(5)**: 1015-1018.
19. Meeker et al., (1989) "An Additional Breakingpoint Region in the BCL-1 Locus Associated with the t(11;14) (q13;q32) translocation of B-lymphocytic Malignancy", Blood, **74(5)**:1801-1806. (Exhibit 3)
20. Motokura, T., et al., (1991) "Arnold, A. a Novel Cyclin Encoded by a *bcl-1* Linked Candidate Oncogene", Nature, **350(6318)**:512-515.
21. Nishida et al., (1989) "Nonrandom Rearrangements of Chromosome 14 at Band q32.33 in Human Lymphoid Malignancies with Premature B-cell Phenotype", Cancer Research, **49(5)**:1275-1281. (Exhibit 4)

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22. Rabbitts, T.H. (1994) "Chromosomal Translocations in Human Cancer", Nature, **372(6502)**:143-149.
23. Rabbitts, P.H., et al., (1988) "Chromosome Abnormalities At 11q13 In B Cell Tumours", Oncogene, **3(1)**:99-103.
24. Rao, P.H., et al., (1994) "Subregional Mapping of 8 Single Copy Loci to Chromosome 6 by Fluorescence in Situ Hybridization", Cytogenet. Cell Genet., **66(4)**:272-273.
25. Seto, M., et al., (1992) "Gene Rearrangement and Overexpression of *PRAD1* in Lymphoid Malignancy With t(11;14)(q13;q32) Translocation", Oncogene, **7(7)**:1401-1406.
26. Sun, Z., and Kitchingman, G.R., (1991) "Sequencing of Selected Regions of the Human Immunoglobulin Heavy-Chain Gene Locus That Completes the Sequence From J_H Through Delta Constant Region", DNA Sequence, **1(5)**:347-355.
27. Taniwaki, M., et al., (1994) "Nonrandom Chromosomal Rearrangements of 14q32.3 and 19p13.3 and Preferential Deletion of lp In 21 Patients With Multiple Myeloma and Plasma Cell Leukemia", Blood, **84(7)**:2283-2290.
28. Tsujimoto, Y., et al., (1985) "Clustering of breakpoints on chromosome 11 in human B-cell neoplasms with the t(11;14) chromosome translocation", Nature, **315(6017)**:340-343.
29. Tsujimoto, Y., et al., (1984) "Molecular Cloning of

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Chromosomal Breakpoint of B-cell Lymphomas and Leukemias With the t(11;14) Chromosome Translocation", Science, **224(4656)**:1403-1406.

30. Veals, S.A., et al., (1992) "Subunit of an Alpha-Interferon-Responsive Transcription Factor is Related to Interferon Regulatory Factor and Myb Families of DNA-binding Proteins", Mol. Cell Biol., **12(8)**:3315-3324.
31. Weh, H.J., et al., (1993) "Karyotype in Multiple Myeloma and Plasma Cell Leukemia", Eur. J. Cancer, **29A(9)**:1269-1273.
32. Yamagata, T., et al., (1996) "A Novel Interferon Regulatory Factor Family Transcription Factor, ICSAT/Pip/LSIRF, That Negatively Regulates the Activity of Interferon-Regulated Genes", Mol. Cell Biol., **16(4)**:1283-1294.
33. Ye, B.H., et al., (1993) "Alterations of a Zinc Finger-Encoding Gene, *BCL-6*, in Diffuse Large-Cell lymphoma", Science, **262(5134)**:747-750.
34. Zhang, X-G., et al., (1994) "Reproducible Obtaining of Human Myeloma Cell Lines as a Model for Tumor Stem Cell Study in Human Multiple Myeloma", Blood **83(12)**:3654-3663.

The subject application is a is a continuation of U.S. Serial No. 08/654,482, filed May 28, 1996, now allowed.

Copies of the documents listed as publications 1, 3-4, 6-14, 16-

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18, 20 and 22-34 were submitted previously to the U.S. Patent and Trademark Office in connection with application U.S. Serial No. 08/654,482, filed on May 28, 1998. Publications 5 and 17 were cited by the Examiner in connection with U.S. Serial No. 08/654,482. Publications 2, 5, 15, 17, 19, 21, and 27 were cited in the International Search Report for PCT International Application No. PCT/US97/09065, filed May 28, 1997, which claims priority of and is a continuation-in-part of U.S. Serial No. 08/654,482. Thus pursuant to 37 C.F.R. §1.98(d), since the subject application claims the benefit of U.S. Serial No. 08/654,482 under 35 U.S.C. §120, copies of the above-listed publications, 1, 3-14, 16-18, 20 and 22-34 are not required to be submitted herewith. A copy of publications 2, 15, 19, and 21 is attached hereto as **Exhibits 1-4**, respectively. A copy of the International Search Report for PCT/US97/09065, is attached as **Exhibit 5**.

Applicant requests that the Examiner review the publications and make them of record in the subject application.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provide below.



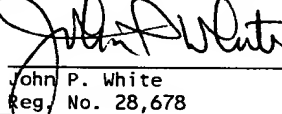
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No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231

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